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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,838	10/15/2001	Ornella Flore		1712

7590 05/02/2006

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,838	FLORE, ORNELLA	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11,13,15,17,19,21,23,25 and 27* is/are allowed.

6)☐ Claim(s) *12,14,16,18,20,22,24,26 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 01/28/04.

The amendment filed 01/28/04 affects the application, 09/976,838 as follows:

1. Claims 1-10 have been canceled. New claims 11-28 have been added. This leaves claims 11-28.
2. The responsive to applicants' arguments is contained herein below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites the phrase "containing a moiety". However, the claim is indefinite because such phrase renders the claim incomplete. It appears that the said phrase should be "contains a moiety".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 14, 16, 22, 24, 26, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kozuka et al. (JP 05306228).

In claim 12, applicant claims a method of treating Epstein Barr virus comprising the steps of administering to the patient a derivative of a triterpenoid acid containing a moiety of glycyrrhetinic acid wherein the moiety of glycyrrhetinic acid inhibits the transcription of viral latent genes. Kozuka et al. disclose applicant's method of treating Epstein-Barr virus early antigen comprising inhibiting the formation of Epstein-Barr virus by administering to a patient a derivative of a triterpenoid acid containing a moiety of glycyrrhetinic acid (glycyrrhetinic acid monoglucuronide salt) (see abstract). It should be noted that since Kozuka et al. treats the same disease or condition by administering the same compound as applicant (to the same patient) then Kozuka et al.'s compound should inherently have the same effect of inhibiting the transcription of viral latent genes. Furthermore, the examiner considers the inhibition of transcription of viral latent genes an effect, mechanism, or mode of action by which said treatment of Epstein Barr occurs. Claims 14 which is drawn to a method according to claim 12 wherein the dosage is about 10 mg to about 50 mg, is anticipated by Kozuka et al. since Kozuka et al. also administers the same dosage (3-300 mg) (see abstract). Claims 16 which is drawn to a method according to claim 12 wherein the dosage is about 50 mg to about 1000 mg, is anticipated by Kozuka et al. since Kozuka et al. also administers the same dosage (3-300 mg) (see abstract). Claim 22 which is drawn to a method according to claim 12 wherein the dosage is applied intravenously, is anticipated by Kozuka et al. since Kozuka et al. also administers their dosage intravenously (see abstract). Claim 24 which is drawn to a method according to claim 12 wherein the dosage is applied parenterally, is anticipated by Kozuka et al. since Kozuka et al. also administers their

dosage parenterally (injection) (see abstract). In claim 26, applicant claims a method of treating Epstein Barr virus according to claim 12 wherein the derivative of a terpenoid acid contains a moiety of a salt of glycyrrhetinic acid. Kozuka et al. disclose applicant's method of treating Epstein Barr virus comprising inhibiting the formation of Epstein-Barr virus by administering a derivative of a triterpenoid acid containing a moiety of a salt of glycyrrhetinic acid (glycyrrhetinic acid monoglucuronide salt) (see abstract). In claim 28, applicant claims "A method of treating Epstein Barr virus comprising the steps of administering to the patient a therapeutic amount of a derivative of a triterpenoid acid containing a moiety of a salt of glycyrrhetinic acid wherein the salt of glycyrrhetinic acid inhibits the expression of latent viral antigens of the Epstein Barr. Kozuka et al. disclose applicant's method of treating Epstein Barr virus comprising inhibiting the formation of Epstein-Barr virus by administering a derivative of a triterpenoid acid containing a moiety of a salt of glycyrrhetinic acid (glycyrrhetinic acid monoglucuronide salt) (see abstract). It should be noted that since Kozuka et al. treats the same disease or condition by administering the same compound as applicant (to the same patient) then Kozuka et al.'s compound should inherently have the same effect of inhibiting the expression of latent viral antigens of the Epstein Barr. Furthermore, the examiner considers the inhibition of the expression of latent viral antigens of the Epstein Barr an effect, mechanism, or mode of action by which said treatment of Epstein Barr occurs.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims ~~12~~, 18, 20, 22, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozuka et al. (JP 05306228).

In claim 12, applicant claims a method of treating Epstein Barr virus comprising the steps of administering to the patient a derivative of a triterpenoid acid containing a moiety of glycyrrhetinic acid wherein the moiety of glycyrrhetinic acid inhibits the transcription of viral latent genes. Claims 14, 16, 18, 20, 22, 24 are drawn to a method of claim 12 wherein specific dosages of said compound is administered to specific patients and wherein the dosage is administered by specific routes.

Kozuka et al. disclose a method of treating Epstein-Barr virus early antigen comprising inhibiting the formation of Epstein-Barr virus by administering a derivative of a triterpenoid acid containing a moiety of glycyrrhetinic acid (glycyrrhetinic acid monoglucuronide salt) (see abstract).

The difference between applicant's claimed method and the method of Kozuka et al. is the dosage and the routes of administration used. However, the use of specific dosages and the routes of administration depend on factors such as the severity of the disease or condition, the age, weight and kind of the patient treated, and is well with the purview of a skilled artisan.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the process of Kozuka et al. to treat Epstein Barr virus by administering glycyrrhetinic acid (glycyrrhetinic acid monoglucuronide salt) to a patient and to use different dosages and routes of administration, depending on factors such as the severity of the Epstein Barr virus, the age, weight and kind of the patient treated.

One having ordinary skill in the art would have been motivated, to use the process of Kozuka et al. to treat Epstein Barr virus by administering glycyrrhetinic acid (glycyrrhetinic acid monoglucuronide salt) to a patient and to use different dosages and routes of administration, depending on factors such as the severity of the Epstein Barr virus, the age, weight and kind of the patient treated.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: The examiner has found claims 11, 13, 15, 17, 19, 21, 23, 25, 27 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates to a method of treating Epstein Barr virus comprising administering to a patient a therapeutic amount of glycyrrhizic acid. Furthermore, the invention relates to a method of treating Epstein Barr virus comprising administering to a patient a derivative of a triterpenoid acid containing a moiety of glycyrrhetinic acid. The very relevant prior art document Kozuka et al. (JP 05306228) to this invention discloses a method of treating Epstein Barr virus using a derivative of a triterpenoid acid containing a moiety of glycyrrhetinic acid. However, although the claims 12, 14, 16, 18, 20, 22, 24, 26, 28, are rejected as being anticipated by or unpatentable over the prior art document (as stated above), the prior art document does not disclose or suggest that glycyrrhizic acid can be used or administered to treat Epstein Barr virus, as recited in claims 11, 13, 15, 17, 19, 21, 23, 25, 27.

Response to Amendment

Applicant's arguments with respect to claims 12, 14, 16, 18, 20, 22, 24, 26, 28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang, Ph.D can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

Michael C. Henry

4/28/06

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

April 27, 2006.